

Application No. 10/767,867
Inventors: DeHart
Application Filed: January 29, 2004
Response to final Office Action mailed April 23, 2009

Remarks/Arguments

Claims 1-10 and 63-69 examined and rejected. By this Amendment, claims 1-3, 63 and 66 are amended and claims 64 and 67-69 are canceled. Claims 11-31, 42-53, 56-58, 61 and 62 were canceled in a previous response. Claims 32-41, 54, 55, 59 and 60 were previously withdrawn in response to a Restriction Requirement. Accordingly, claims 1-10 and 63, 65 and 66 are now pending in the application.

The amendments to the claims are fully supported by the specification and the figures, in particular paragraphs [0038] and [0039]. Accordingly, no new matter has been added. Reconsideration and allowance of the claims as amended is respectfully requested in view of the comments made below.

I. Anticipation Rejection

Claims 1-10 and 63-69 have been again rejected under 35 USC §102(b) as allegedly being anticipated by Humphrey et al. (US 5,607,401). See Office Action, p. 4.

Claims 1, 2 and 63-69

The rejection of claims 64 and 67-69 is moot as the claims have been canceled. Independent claims 1 and 63 (and claims 2, 65 and 66 dependent thereon or having a chain of dependency thereto) recite in part a lancet device comprising a lancet including a seamless member, wherein the seamless member is sufficiently rigid to penetrate skin without augmentation.

Humphrey discloses a "flexible, polymeric piercing member." (Col. 6, line 59) An "augmenting means stiffens the piercing member," (Col. 7, lines 9-10) making "it possible for the polymeric hypodermic lancet to pierce the skin, a function that the lancet would otherwise be unable to do unaided." (Col. 7, lines 54-57. See also col. 8, lines 49-53). Therefore, Humphrey does not teach or suggest a lancet having a seamless member sufficiently rigid to penetrate skin without augmentation, as required

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by claim 1. For at least this reason, Humphrey does not anticipate claims 1 and 63 and by their dependencies claims 2, 65 and 66.

Claims 3-10

Independent claim 3 (and claims 4-10 dependent thereon or having a chain of dependency thereto) recites a lancet device comprising a lancet including a unitary stainless steel member which is hollowed along at least a portion of its length, the unitary stainless steel member including a first end and a second end, wherein the first end of the unitary member includes first and second ground surfaces which at least partially define first and second sharpened tips. A lancet holder is arranged and configured on the second end of the lancet to move the lancet to penetrate the skin of a patient with the first and second sharpened tips.

Humphrey discloses a "flexible, polymeric piercing member." (Col. 6, line 59; see also col. 10, lines 52-54) Humphrey does not teach or suggest a unitary stainless steel member.

Humphrey discloses that the lancet is pushed through skin and into the subcutaneous tissue. The depth of the piercing process can be controlled so that the lancet stopped before "making contact with the supporting base structure. (Col. 8, lines 49-56) Humphrey does not teach or suggest only penetrating the skin of a patient with the first and second sharpened tips, as recited in the claim and discussed in paragraph [0048] of the specification.

For at least these reasons, Humphrey does not anticipate claim 3 and by their dependencies claims 4-10.

II. Obviousness Rejections

Claims 1-10 and 63-69 are rejected as allegedly being obvious under 35 USC §103(a) over Ayres (US 3,906,932), in view of Boothroyd (Geoffrey Boothroyd, Peter Dewhurst, Winston Knight, Product Design for Manufacture and Assembly, 1994,

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Marcel Dekker, Inc. pages 64 and 165). See Office Action, p. 6. The rejection of claims 64 and 67-69 is moot as the claims have been canceled.

Applicant again submits that Boothroyd is non-analogous art even in light of KSR. Boothroyd discloses that for ease of handling an assembly component during an assembly process, the assembly components should be designed to have end-to-end symmetry. This symmetry helps prevent jamming or tangling when components are stored in bulk. (Pg. 64). Boothroyd also indicates that such design considerations are vital to high-speed automatic and robot assembly. (Pg. 165). On page 3 of the Office Action in his Response to Arguments, the Examiner states that it is old and well known that automation assembly results in low cost and larger quantity as compared to a manual assembly. Applicant does not know the relevance of this argument. Applicant's lancet is designed to reduce pain to the patient while ensuring the collection of an adequate amount of blood. The process of manufacturing the lancets recited in the claims is clearly disclosed in the specification. Grinding an additional end of the lancet would certainly add time and cost to the process.

Furthermore, the tips of the needle disclosed in Ayres are used to penetrate very different material, as noted by the Examiner on page 7 of the Office Action. Boothroyd is clearly not aimed at components that have different uses at the symmetrical ends. Boothroyd illustrates dowels as a symmetrical component. The Applicant fails to see the relevance of the Boothroyd reference as it is not from the field of lancets or any related medical device field, is not reasonably pertinent to the problems addressed by the invention as Boothroyd does not address blood flow and patient pain, and logically would not have commanded itself to an inventor's attention in considering the problems because of the matter with which Boothroyd deals, namely decreasing problems with automated assembly systems. In addition, the level of ordinary skill in the pertinent art of lancet design is different than the level of ordinary skill in the art of designing for ease of automatic assembly processes. Therefore, the Boothroyd reference is non-

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analogous art and cannot be used in combination with Ayres or any other reference to render the claims obvious.

For the sake of argument, if Boothroyd was analogous art, the Examiner has failed to make a *prima facie* case of obviousness. The Examiner contends that Ayres discloses the limitations of the independent claims 1, 3 and 63 but fails to disclose both ends of the needle having the same needle point design. Applicant asserts that Ayres also does not disclose a lancet holder arranged and configured on the second end of the lancet to move the lancet to penetrate the skin of a patient with the first and second sharpened tips.

The Examiner contends on page 7 of the Office Action that the teaching by the Boothroyd reference of the benefits of symmetrical design would render the claims obvious because one of ordinary skill in the art would use the tip of Ayres on both ends to achieve the same advantages. In addition, the Boothroyd reference would need to teach or suggest to one of ordinary skill in the art to only penetrate the skin of a patient with the tips of the lancet.

The needle in Ayres was designed to penetrate the rubber stopper of a Vacutainer. The needle in Ayres addressed the problems of needle deflection when entering the stopper and coring of the stopper. (Abstract, Col. 1, lines 36-50). To avoid deflection and coring, Ayres teaches bending the sharp tips of the needle shown in Fig. 1 inward in abutting relationship, as shown in Figs. 2, 4 and 8. (Col. 2, lines 30-35). Therefore, Ayres teaches that the needle shown in Fig. 1 is not desirable. As stated on page 3 of the Office Action, the Examiner is relying on Fig. 1 for his rejection. On page 7 of the Office Action, the Examiner states that for ease of handling a component the component should be designed to have end-to-end symmetry, realizing the same advantages of the needle point on both ends. The Examiner has failed to point out why one skilled in the art would look to Boothroyd to make a needle having the undesirable

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needle tip of Ayres at both ends. It should be noted that the tips disclosed as desirable in Ayers would inhibit blood flow and likely be more painful to the patient.

In addition, Independent claims 1, 3 and 63 (and claims 2-10, 65 and 66 dependent thereon or having a chain of dependency thereto) each recite at least a lancet device comprising a lancet including first and second sharpened tips and a lancet holder arranged and configured on the second end of the lancet to move the lancet to penetrate the skin of a patient with the first and second sharpened tips.

As shown in Fig. 5 of Ayres, the needle penetrates through the stopper up to part of the needle's shaft. There is not teaching or suggestion of only penetrating the sharpened tips of the lancet into the stopper, so there can be no teaching or suggestion of only penetrating the sharpened tips of the lancet into skin. Boothroyd in no way addresses this. Therefore, the combination fails to teach, suggest or render obvious moving the lancet to penetrate the skin of a patient with first and second sharpened tips.

For these reasons at least, the combination of Ayres and Boothroyd does not teach, suggest or render obvious claims 1-10, 63, 65 and 66.

For the reasons set forth above, Applicant traverses the Examiner's rejections and respectfully submits that all pending claims are allowable. Applicant requests the Examiner's early examination of the pending claims in the present application. In the event that the Examiner deems a telephonic discussion would be helpful in advancing the prosecution of the present application, Applicants respectfully request the Examiner to contact Applicants' representative at (248) 244-0163.

Respectfully submitted,

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